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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/282,471	03/31/1999	INDU PARIKH	121-161	8677

7590

01/30/2002

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/282,471

Applicant(s)

Parikh

Examiner

Susan Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Dec 14, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise ~~new~~ issues that would require further consideration ~~and/or search~~. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: see attachment

4. ☐ Applicant's reply has overcome the following rejection(s): _____
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: _____
- Claim(s) objected to: _____
- Claim(s) rejected: 1-15
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

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ATTACHMENT

Receipt is acknowledged of applicants Declaration filed 05/13/99, Information Disclosure Statement with Attachment filed 06/30/99 and 11/08/00, Amendment A filed 11/08/00, Extension of Time filed 12/14/01, Notice of Appeal filed 12/14/01, and Amendment B filed 12/14/01.

Response to Arguments

1. Applicant's arguments filed 12/14/01 have been fully considered but they are not persuasive. The examiner maintains the original rejections, and thus:
2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duclos et al. US 5,776,495, in view of Ecanow US 4,963,367.

Applicant argues that Duclos does not teach coating or adhering phospholipid and surfactant onto the surfaces of the fenofibrate particles to prevent particles from aggregating or flocculating. Contrary to the applicant's argument, the rejected claims are product claims. Even though the product claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its process of production. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Duclos obtains a product desired by the applicant, e.g., fine powder or granules of fenofibrate that appeared to be very dry, were ground and sieved (column 17, lines 26-34).

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Accordingly, the fenofibrate powder or granules of Duclos are free flowing, and non-agglomerating.

3. Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duclos et al. ('495), in view of Ecanow ('367) and Haynes US 5,091,187.

Applicant argues that Ecanow's process including coacervate-based that does not disclose by the applicant. However, applicant's claim language does not exclude that. Furthermore, Ecanow's process also obtain the product desire by applicant, that is a drug delivery compositions yield new and unexpected degrees of stabilization (see abstract). The burden is shifted to applicant to establish that Ecanow's process have a detrimental effect upon the desirability of forming a stable composition.

Haynes is relied upon solely for the teaching of the process to prepare fenofibrate particles.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

- JPMAN K. PAGE
PATENT EXAMINER
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